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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/023,427	12/12/2001	Harshal P. Bhagwatwar	U 013528-7	2278

140 7590 08/19/2003

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

DI NOLA BARON, LILIANA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/023,427

Applicant(s)

BHAGWATWAR ET AL.

Examiner

Liliana Di Nola-Baron

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2001.
- 2a) ☐ This action is **FINAL**.
- 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17, 52, 54, 55 and 63, drawn to a composition comprising a polymer, a delivery system formed from said composition and a method of treatment comprising administering said composition classified in class 424, subclass 489.
 - II. Claims 18-28, 56, 57 and 66-68, drawn to a process for the preparation of a composition, classified in class 427, subclass 213.
 - III. Claims 29-40, 53, 58, 59 and 64, drawn to a kit comprising a composition and a device and a method of treatment comprising said kit, classified in class 424, subclass 422.
 - IV. Claims 41-51, 60-62 and 65, drawn to a method of forming in situ a delivery system, classified in class 424, subclass 426.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the compositions claimed in Group I may be formed by a process comprising the step of dissolving the emulsifier in an aqueous phase, rather than in oil, as claimed in the process of Group II.

3. Inventions III and I are related as mutually exclusive species in an intermediate-final product relationship. Distinctness is proven for claims in this relationship if the intermediate product is useful to make other than the final product (MPEP § 806.04(b), 3rd paragraph), and the species are patentably distinct (MPEP § 806.04(h)). In the instant case, the intermediate product of Group I is deemed to be useful as controlled-release drug delivery system and the inventions are deemed patentably distinct since there is nothing on this record to show them to be obvious variants. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions anticipated by the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

4. Inventions IV and I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed in Group IV, namely forming in situ a delivery system, can be achieved using polymer compositions having reverse gelling properties.

5. Inventions III and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the

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compositions claimed in Group III may be formed by a process comprising the step of dissolving the emulsifier in an aqueous phase, rather than in oil, as claimed in the process of Group II.

6. Inventions IV and II are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

7. Inventions IV and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed in Group IV, namely forming in situ a delivery system, can be achieved using polymer compositions having reverse gelling properties.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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9. This application contains claims directed to the following patentably distinct species of the claimed biodegradable polymer:

1. polylactides
2. polyglycolides
3. polylactics
4. polylactic acid-co-glycolic acid
5. polylactide-co-glycolides
6. polyesteramides
7. star-branched polymers
8. polyphosphoesters
9. albumin
10. fibrin
11. fibrinogen combinations
12. polycaprolactones
13. polydioxanones
14. polycarbonates
15. polyhydroxybutyrates
16. polyalkylene oxalates
17. polyanhydrides
18. polyamides
19. polyurethanes
20. polyacetals

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21. polyketals
22. polyorthocarbonates
23. polyphosphazenes
24. polyhydroxyvalerates
25. polyalkylene succinates
26. poly(malic acid)
27. poly(amino acids)
28. chitin
29. chitosan
30. polyorthoesters
31. gelatin
32. collagen
33. polyethylene glycols
34. polyethylene oxides
35. polypropylene oxides
36. polyethers
37. betacyclodextrin
38. polysaccharides
39. polyvinyl alcohol
40. polyvinyl pyrrolidone
41. polyoxyethylene-polypropylene block copolymers

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Applicant is required under 35 U.S.C. 121 to elect a biodegradable or a non-biodegradable polymer. In the case that Applicant elects a biodegradable polymer, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of the biodegradable polymer listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 18, 29 and 41 are generic.

10. This application contains claims directed to the following patentably distinct species of the claimed non-biodegradable polymer:

1. ethyl celluloses
2. acrylates
3. methacrylates
4. pyrrolidones
5. polyoxyethylenes
6. polyoxyethylene-polypropylene copolymers
7. hydroxypropylmethyl celluloses
8. hydroxypropyl celluloses
9. methyl celluloses
10. polymethylmethacrylates
11. cellulose acetates
12. shellac
13. methacrylic acid based polymers

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Applicant is required under 35 U.S.C. 121 to elect a biodegradable or a non-biodegradable polymer. In the case that Applicant elects a non-biodegradable polymer, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of the non-biodegradable polymer listed above for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 18, 29 and 41 are generic.

8. This application contains claims directed to the following patentably distinct species of the claimed solvent:

1. N-methyl-2-pyrrolidone
2. NN'-dimethylacetamide
3. water
4. 2-pyrrolidone
5. sorbitol
6. dimethyl sulfoxide
7. dimethylformamide
8. glycofural
9. glycerolformal
10. propylene glycol
11. polyethylene glycol
12. glycerol
13. caprolactam
14. decylmethyl sulfoxide

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15. ethanol

16. dialkylamides

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of the solvent for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 18, 29 and 41 are generic.

11. This application contains claims directed to the following patentably distinct species of the claimed biologically active agent:

1. peptides
2. proteins
3. desensitizing agents
4. antigens
5. vaccines
6. anti-infectives
7. antibiotics
8. antimicrobials
9. antineoplastics
10. antitumor
11. antiallergenics
12. steroidal anti-inflammatory agents
13. analgesics

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14. decongestants
15. miotics
16. anticholinergics
17. sympathomimetics
18. sedatives
19. hypnotics
20. antipsychotics
21. psychic energizers
22. tranquilizers
23. androgenic steroids
24. estrogens
25. progestational agents
26. humoral agents
27. prostaglandins
28. antispasmodics
29. antimalarials
30. antihistamines
31. cardioactive agents
32. non-steroidal anti-inflammatory agents
33. antiparkinsonian agents
34. antihypertensive agents
35. beta-adrenergic blocking agents

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36. nutritional agents
37. antivirals
38. DNA fragments
39. nucleic acids
40. genetic material
41. oligonucleotides
42. radioisotopes
43. leuprolide acetate
44. goserelin acetate
45. octeotride acetate
46. paclitaxel
47. chlorpheniramine maleate
48. trimethoprim
49. sulfamethoxazole
50. lactic acid
51. pseudoephedrine hydrochloride
52. olanzapine
53. captopril
54. lidocaine hydrochloride
55. felodipine
56. indomethacin
57. povidone iodine

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58. terbutaline sulfate

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of the biologically active agent for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 7, 24, 25, 35, 36, 46 and 63-68 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

12. A telephone call was made to Attorney Janet Cord on August 11, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lilitiana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

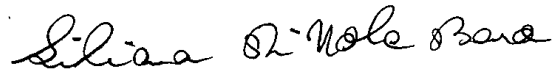
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.



August 12, 2003

Liliana Di Nola-Baron

Patent Examiner

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